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EXAMINER	
ZHENG, LI	
ART UNIT	PAPER NUMBER
1638	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,980	VAN DER VOSSEN ET AL.	
	Examiner	Art Unit	
	Li Zheng	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *8-38 and 40-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 February 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some.* c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4272006/252007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-7 and 39, and SEQ ID NO: 1 and 2 in the reply filed on 3/19/2007 is acknowledged. Applicants argue that RGA2 gene of Song et al. is not an Rpi-blb2 protein because the degree of identity between blb2 (the protein of instant invention) and blb1 (the protein encoded by RGA2) is only 17.1%. However, according to definition in the specification (page 4, lines 28-30), the "Rpi-blb2 protein" relates to a protein or polypeptide which expression in a plant or a part confers resistance of the plant or a part of the plant to one of the pathogens described herein in comparison to a non-resistant strain. Therefore, blb1 protein of Song et al. meets the definition of "Rpi-blb2 protein". Applicants further traverse the restriction requirement for electing a single nucleotide sequence and a single protein sequence by arguing that the nucleotide sequences of SEQ ID NO: 3, 5 and 6 comprise SEQ ID NO: 1 and SEQ ID NO: 2 and 4 are corresponding protein sequence. The Applicants' argument is found partially persuasive. As a result the restriction requirement for electing a single polypeptide sequence and restrictions among SEQ ID NO: 3, 5 and 6 are withdrawn. However, since none of the SEQ ID NO: 3, 5, and 6 comprise SEQ ID NO: 1 due to the presence of intron sequence, SEQ ID NO: 1 and SEQ ID NO: 3, 5 & 6 are considered as patentably distinct nucleotide sequences, which also required separate sequence search for prior art.

Applicants are advised that since the restriction between SEQ ID NO: 2 and 4 and the restriction among SEQ ID NO: 3, 5 and 6 are withdrawn, if any claim(s) that include(s) the limitation of the examined claims is/are presented in a continuation or divisional application, the claim of the application may be subject to a provisional statutory and/or nonstatutory double patenting rejection over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 no longer apply. MPEP804.01.

The requirement is still deemed proper and is therefore made FINAL.

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The numerous hyperlinks shown on the specification page 6, page19, and page 71 need to be disabled.

3. The specification is objected to under 37 CFR 1.821(d) as failing to refer to a sequence by use of its sequence identifier preceded by "SEQ ID NO:". The nucleotide/polypeptide sequences in Figures 13 A-D, 14, 15 and 17 should be identified

as SEQ ID NOs. Alternatively, the brief descriptions of those figures on pages 79-80 can be amended to recite the identifiers.

4. The Figure 16 is objected to because the nucleic acids alignment is missing.

5. The specification is objected under 37 CFR 1.821(d) as failing to refer to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the specification on page 92, line 35 as well as the primer sequences in Table 3A and 3B.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-7 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1: the recitation, "a plant", in last line of the claim renders the claim indefinite. It is unclear what the recitation refers to. The metes and bounds are not clear. It is suggested to replace the recitation with – the plant --.

In claim 2: the recitation, "several amino acids", in part (d) renders the claim indefinite. It is unclear what the recitation, "several amino acids", encompasses and how many modifications are allowed. The metes and bounds are not clear. Further, the recitation, "epitope-bearing portion", renders the claim indefinite. It is unclear what the recitation encompasses. The metes and bounds are not clear. For examination purpose, "epitope-bearing" is not given any weight. Still further, for part (h), it is unclear what the protein fragment it encompasses. Particularly, it is unclear what are the combinations of the starting residue and the ending residue for the claimed fragments of polypeptides. Furthermore, the recitation, "stringent condition", in part (k) renders the claim indefinite. The term, "stringent" is a relative term with no definite meaning. It is unclear what is considered to a stringent condition. The metes and bounds are not clear. Finally, the recitation, "or expressing a polypeptide encoded by a segment of chromosome or linkage group 6 of Solanum bulbocastanum or Solanum tuberosum which co-segregates with a marker selected from table 3a or 3b and which mediates resistance to a pathogen of the phylum Oomyceta and whereby the polynucleotide does not have the sequence of Mil.1 or Mil.2 as depicted in SEQ ID NO: 7 or 9", at the end of the claim renders the claim indefinite. It is unclear what the recitation intends to modify. The metes and bounds are not clear.

In claim 4: the recitation, "activity", in line 1 of the claim renders the claim indefinite. It is unclear what the recitation refers to. The metes and bounds are not clear. It is suggested to replace the recitation with – the activity--.

Claim 5 recites the limitation " the endogenous activity" and "the further resistance protein" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 6 recites the limitation, "the resistance protein", in part a)-g). There is insufficient antecedent basis for this limitation in the claim. It is suggest to replace the recitation with – the Rpi-blb2 protein--.

Claim 7 recites the limitation " the sporulation index". There is insufficient antecedent basis for this limitation in the claim. Further, it is unclear what the recitation encompasses. The metes and bounds are not clear.

7. Claims 1-7 and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A review of the full content of the specification indicates that to obtain 1) nucleic acid molecule encoding a polypeptide derived from SEQ ID NO: 2 or 4 by way of substitution, deletion and/or addition of one or several amino acids of the amino acid sequence of SEQ ID NO: 2 or 4; 2) nucleic acid molecule encoding a polypeptide the

sequence of which has an identity of 70% or more to the amino acid sequence of SEQ ID NO: 2 or 4; 3) nucleic acid molecule comprising a fragment or a epitope-bearing portion of a polypeptide encoded by a nucleic acid molecule of any one of SEQ ID NO: 2 or 4 encoding nucleotide sequences and nucleotide sequences of 1)-2); 4) nucleic acid molecule comprising a polynucleotide having a sequence of a nucleic acid molecule amplified from a nucleic acid library using a primer as listed in Table. 3b; 5) nucleic acid molecule encoding a fragment beginning with amino acid: 1, 30, 50, 100, 200, 300, 500, or 1000 and stopping with amino acid 1276, 1000, 500, 300, 200, 50, or 1 of a polypeptide encoded by any one of SEQ ID NO: 1 and nucleotide sequences of 1)-4); 6) nucleic acid molecule comprising at least 20 nucleotides of a polynucleotide of any one of SEQ ID NO: 2 or 4 encoding nucleotide sequences and nucleotide sequences of 1)-5); 7) nucleic acid molecule encoding a polypeptide being recognized by a monoclonal antibody that have been raised against a polypeptide encoded by SEQ ID NO: 1 or any nucleotide sequences of 1)-6); 8) nucleic acid molecule obtainable by screening an appropriate library under stringent conditions with a probe having the sequence of the nucleic acid molecule of any one of SEQ ID NO: 2 or 4 encoding nucleotide sequences and nucleotide sequences of 1)-7), or of a fragment thereof of at least 20; 9) nucleic acid molecule the complementary strand of which hybridises under stringent conditions with a nucleic acid molecule of any one of SEQ ID NO: 2 or 4 encoding nucleotide sequences and nucleotide sequences of 1)-8) or the complementary strand thereof; and 10) any Rpi-blb2 protein are essential to the operation of the claimed invention.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." (See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997)). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

A review of the language of claim 3 indicates that the claim is broadly drawn to a genus of 1) nucleic acid molecule encoding a polypeptide derived from SEQ ID NO: 2 or 4 by way of substitution, deletion and/or addition of one or several amino acids of the amino acid sequence of SEQ ID NO: 2 or 4; 2) nucleic acid molecule encoding a polypeptide the sequence of which has an identity of 70% or more to the amino acid sequence of SEQ ID NO: 2 or 4; 3) nucleic acid molecule comprising a fragment or a epitope-bearing portion of a polypeptide encoded by a nucleic acid molecule of any one of SEQ ID NO: 2 or 4 encoding nucleotide sequences and nucleotide sequences of 1)-2); 4) nucleic acid molecule comprising a polynucleotide having a sequence of a nucleic acid molecule amplified from a nucleic acid library using a primer as listed in Table. 3b; 5) nucleic acid molecule encoding a fragment beginning with amino acid: 1, 30, 50, 100,

200, 300, 500, or 1000 and stopping with amino acid 1276, 1000, 500, 300, 200, 50, or 1 of a polypeptide encoded by any one of SEQ ID NO: 1 and nucleotide sequences of 1)-4); 6) nucleic acid molecule comprising at least 20 nucleotides of a polynucleotide of any one of SEQ ID NO: 2 or 4 encoding nucleotide sequences and nucleotide sequences of 1)-5); 7) nucleic acid molecule encoding a polypeptide being recognized by a monoclonal antibody that have been raised against a polypeptide encoded by SEQ ID NO: 1 or any nucleotide sequences of 1)-6); 8) nucleic acid molecule obtainable by screening an appropriate library under stringent conditions with a probe having the sequence of the nucleic acid molecule of any one of SEQ ID NO: 2 or 4 encoding nucleotide sequences and nucleotide sequences of 1)-7), or of a fragment thereof of at least 20; 9) nucleic acid molecule the complementary strand of which hybridises under stringent conditions with a nucleic acid molecule of any one of SEQ ID NO: 2 or 4 encoding nucleotide sequences and nucleotide sequences of 1)-8) or the complementary strand thereof; and 10) any Rpi-blb2 protein. However, the specification also does not describes any other species in the claimed genus except for SEQ ID NO: 1, 3, 5 and 6 encoding SEQ ID NO: 2 or 4. Neither the specification nor the prior teaches the conserved structures of SEQ ID NO: 2 or 4 that are essential for its anti-Oomycete activity. The only polypeptide structure correlated with the anti-Oomycete activity is the sequence of SEQ ID NO: 2 or 4 encoded by SEQ ID NO: 1, 3, 5 or 6. Not a single specie differing in amino acid sequence from SEQ ID NO: 2 or 4 and having anti-Oomycete activity is described in the specification. Therefore it is unclear what is the conserved structure of those modified polypeptides of SEQ ID NO: 2 or 4 encoded

by the instant nucleotide sequences. Therefore, given the lack of enough description, a person skilled in the art would conclude that applicants are not in possession of the whole claimed genus of nucleotide sequences.

8. Claims 1-7 and 39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for increasing resistance of a plant to a plant pathogen of Oomycete by overexpression of a transgene encoding a Rpi-blb2 protein of SEQ ID NO: 2 or 4, does not reasonably provide enablement for nucleotide sequences encoding any Rpi-blb2 proteins, or any nucleotide sequences encoding any variant of SEQ ID NO: 2 or 4 as described in d)-l) of claim 2, or increasing activity of SEQ ID NO: 2 or 4 by others meanings including steps a)-e) of claim 6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The specification teaches genetic mapping of the Rpi-blb2 resistance locus of a potato late-blight resistant line and positional cloning of the RGA5 gene encoding an anti-Oomycetes Rpi-blb2 protein of SEQ ID NO: 2 or 4 (page 82-91). The specification also demonstrates that the transgene of RGC5 can confer resistance to Phytophothora infestans to the susceptible potato and tomato plants (page 91, line 15 – page 92, line 2). The deduced amino acid sequence of Rpi-blb2 gene contains 1267 amino acids and several functional motifs present in R genes of the NBS-LRR class of plant R genes are apparent in the protein. BLAST searches find that the Rpi-blb2 protein of SEQ ID NO: 2

or 4 has the highest homology to Mi-1.1 (82% identity) and Mi-1.2 (81% identity) (page 92-93). The specification also proposes to amplify by PCR alleles of Rpi-blb2 from any Solanum species using primers ARF1F and ARF1R (page 93, lines 31-33).

First, the specification only provide guidance on increasing disease resistance for a plant by expressing an anti-Oomycete protein of SEQ ID NO: 2 or 4. As discussed above, given the broadest and reasonable interpretation of "Rpi-blb2" as a protein or polypeptide which expression in a plant or a part confers resistance of the plant or a part of the plant to one of the pathogens described herein in comparison to a non-resistant strain, the claim encompass any anti-Oomyces protein including those protein unrelated to SEQ ID NO: 2 or 4. The specification provide no guidance on using any anti-Oomyces proteins other than SEQ ID NO: 2 or 4. Undue experimentation would be required for a person skilled in the art to practice the invention using any anti-Oomyces proteins.

Further, as discussed above, neither the specification nor the prior teaches the conserved structures of SEQ ID NO: 2 or 4 that are essential for its anti-Oomycete activity. The specification teaches that the Rpi-blb2 protein of SEQ ID NO: 2 or 4 has the highest homology to Mi-1.1 (82% identity) and Mi-1.2 (81% identity), however, the latter sequence confers resistance to nematodes instead of Oomycets (page 92-93).

Further, Falcon-Perez JM et al. (1999, *J Biol Chem.* 274:23584-90) teach that when twenty-two single amino acid substitutions or deletions were made by site-directed mutagenesis in the nucleotide binding domains, the proposed regulatory domain, and the fourth cytoplasmic loop of the yeast cadmium factor (Ycf1p) vacuolar

protein, two conserved amino acid residues, Glu(709) and Asp(821), were found to be unnecessary for Ycf1p biogenesis and function. Further, Veronese et al. (2003, *Plant Physiology* 131:1580-1590) teach that homologous antimicrobial proteins from a plant species differ in their toxicity to the same microbe (page 1582, last paragraph). It is, thus, unclear which consensus sequence is required to distinguish antifungal protein from others. Therefore, the instant specification fails to provide guidance for which amino acids encoded by SEQ ID NO: 68 can be altered and to which other amino acids, and which amino acids must not be changed, to maintain antifungal activity of the encoded protein. The specification also fails to provide guidance for which amino acids can be deleted and which regions of the protein can tolerate insertions and still produce a functional enzyme.

Making "conservative" substitutions (*e.g.*, substituting one polar amino acid for another, or one acidic one for another) does not produce predictable results. Lazar et al. (1988, Mol. Cell. Biol. 8:1247-1252) teach that the "conservative" substitution of glutamic acid for aspartic acid at position 47 reduced biological function of transforming growth factor alpha while "nonconservative" substitutions with alanine or asparagine had no effect (abstract). Similarly, Hill et al (1998, Biochem. Biophys. Res. Comm. 244:573-577) teach that when three histidines that are maintained in ADP-glucose pyrophosphorylase across several species are substituted with the "nonconservative" amino acid glutamine, there is little effect on enzyme activity, while the substitution of one of those histidines with the "conservative" amino acid arginine drastically reduced

enzyme activity (see Table 1). All these mutated proteins would have at least 95% identity to the original protein.

Therefore, undue experimentation would be required for a person skilled in the art to practice the invention using nucleotide sequences encoding variants of SEQ ID NO: 2 or 4 as described in d)-l) of claim 2.

Still further, with undefined stringent hybridization any DNA could hybridize with SEQ ID NO: 2 encoding nucleotide sequences. Even if the stringent condition is well defined, the state-of-the-art teaches isolating DNA fragments using stringent hybridization conditions, does not always select for DNA fragments whose contiguous nucleotide sequence is the same or nearly the same as the probe. Fourgoux-Nicol et al (1999, Plant Molecular Biology 40 :857-872) teach the isolation of a 674bp fragment using a 497bp probe incorporating stringent hybridization conditions comprising three consecutive 30 minute rinses in 2X, 1X and 0.1X SSC with 0.1% SDS at 65^0C (page 859, left column, 2^{nd} paragraph). Fourgoux-Nicol et al also teach that the probe and isolated DNA fragment exhibited a number of sequence differences comprising a 99bp insertion and a single nucleotide gap, while the DNA fragment contained 2 single nucleotide gaps and together the fragments contained 27 nucleotides mismatches. Taking into account the insertions, gaps and mismatches, the longest stretch of contiguous nucleotides to which the probe could hybridize consisted of 93bp of DNA (page 862, Figure 2). In the present example, the isolated fragment of Frourgoux-Nicol et al exhibits less than 50% sequence identity with the probe to which the fragment hybridized. Furthermore, the specification did not indicate that reverse complement

DNA strands of SEQ ID No. 1, 3, 5 or 6 also encode proteins with anti-Oomycete activity; so DNA hybrizable to SEQ ID NO: 2 encoding nucleotide sequences is expected to be reverse complement to those sequences and therefore is unlikely to encode an anti-Oomycete protein.

Further for part (j) of claim 2, if monoclonal antibody raised against non-essential part of the SEQ ID NO: 2 or 4, the nucleotide sequence encoding a polypeptide being recognized by the monoclonal antibody may have nothing to do with the anti-Oomycete protein. Since the essential structure of SEQ ID NO: 2 or 4 is not taught by the specification, the part (j) is not enabled. The same argument also holds for part (f)(g)(i)(k)(l) of claim 2.

Still further, for part (g) of claim 2, it is well known in the art that PCR amplification generally needs a pair of primers, therefore using "a primer" to amplify alleles of Rpi-blb2 is clearly not enabled. Furthermore, the specification only proposes to amplify by PCR alleles of Rpi-blb2 from any Solanum species using primers ARF1F and ARF1R (page 93, lines 31-33). The specification provide no guidance on combination of primers to form primer pairs to amplify alleles of Rpi-blb2 from any Solanum species. Even for the pair of ARF1F and ARF1R, it is still not enabled because there is no evidence that the primer set can be used to specifically amplify alleles of Rpi-blb2 from any other Solanum species. Undue experimentation would be required for a person skilled in the art to practice the invention by using the nucleotide sequences comprising a polynucleotide having a sequence amplified from nucleotide sequence library using primer pairs as listed in Table 3b.

Finally, increasing the activity of Rpi-blb2 protein can be achieved in many ways including the meanings listed in steps a)-g) of claim6. However, the specification only teach how to practice the invention by expressing anti-Oomycete protein of SEQ ID NO: 2 as a transgene in transgenic plant. The specification is silent as to how to use other methods to increase the activity of Rpi-blb2 protein. For example, the specification does not provide guidance on which genes are involved in up-regulating the expression of Rpi-blb2 protein (part (d) of claim 6), what exogenous inducing factors are (part (e) of claim 6), how to increasing specific activity/stability of the Rpi-blb2 protein (part (a) and (c) of claim 6), or how to stabilize the mRNA encoding resistance gene (part (b) of claim 6). Undue experimentation would be required to practice the invention using ways other than transgenically expressing Rpi-blb2 protein. See *Genentech Inc. v. Novo Nordisk,* A/S (CA FC) 42 USPQ2d 1001 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Given the claim breadth, unpredictability of the art, and lack of further guidance and additional working examples, undue experimentation would be required by one skilled in the art to practice the invention in full scope.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-2, 4-6 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Ballova et al. (2002, The Plant Journal 30:361-371).

Ballvora et al. teach positional cloning of R1 gene for potato resistance to late blight. The BAC clone BA87d17 containing R1 gene is able to confer disease resistance to susceptible cultivar Ddsiree (page 363, the paragraph bridging the left column and the right column). R1 gene has a putative NBS domain consisting of P-loop (amino acids 572-578), kinase 2 and kinase 3a motifs (page 365, the paragraph bridging the left column and the right column, also Figure 4b). According to the alignment between R1 and SEQ ID NO: 2 (result attached), R1 gene meets the limitations set forth in part (d), (f), (i), (j), (k) and (l) of claim 2.

10. Claim 7 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ballova et al. (2002, The Plant Journal 30:361-371).

Claim 7 requires a method for generating resistance to pathogenic Oomycete which has/have a property or characteristic of being able to result in reduction in the sporulation index of at least 30% after infection with P. infestans. Reference of Ballova et al. teaches the method as claimed in the instant application but does not mention the characteristic or property of being able to result in reduction in the sporulation index of at least 30% after infection with P. infestans as claimed. The examiner is unable to determine whether the prior art disclosure possesses the unrecited characteristics or

property. See *In re Best* 195 USPQ 430, 433 (CCPA 1977). The examiner is not in a position to make a conclusion of "inherency/anticipation" or "obviousness" since the record does not allow one to determine if and how the claimed subject matter differ from the prior art. Accordingly, the burden shifts to the Applicant to provide evidence that the prior art neither anticipates nor renders obvious the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-7 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ballova et al. (2002, The Plant Journal 30:361-371) in view of Osusky et al (2000, Nature Biotechnology 18:1162-1166) .

The teaching of Ballova et al. is discussed above.

Ballova et al. do not teaching increasing activity of a further resistance protein.

Osusky et al. teach that transgenic potato plants expressing Cationic antimicrobial peptides (CAPs) exhibit increased resistance to Erwinia carotovora, Fusarium solani as well as Phytophothora cactorum (page 1164, paragraphs 2-4 of left column).

It would have been obvious for a person with ordinary skill in the art to generate a transgenic potato expressing both disease resistance proteins of Ballova et al. and Osusky et al. One would have been motivated to do so given that such transgenic potato plants would show resistance to all the pathogens tested by either Ballova et al. and Osusky et al. It is desirable to generate a potato cultivar that is resistance to a broad spectrum of pathogens including the most important pathogen, Phytophothora infestans.

Conclusion

Claims 1-7 and 39 are rejected. However, SEQ ID NO: 1, 2 and 4 are free of prior art.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ELIZABETH MCELWAIN
PRIMARY EXAMINER